PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application: Silverberg et al.)	Group Art Unit: 1755
)	
Serial No. 09/955,644)	Examiner: Isis A. D. Ghali
)	
Filed: September 18, 2001)	Atty. Docket No. 1893
)	

For: NON-REACTIVE ADHESIVE USEFUL IN TRANSDERMAL DRUG DELIVERY SYSTEMS

DECLARATION UNDER 37 C.F.R. § 1.131

Commissioner for Patents Alexandria, VA 22313-1450

Sir:

We, Eric Silverberg, Rama Chandran, Paul Foreman, Michael Philbin and Smita Shah, hereby declare:

That we are the inventors of the subject matter claimed in subject application Serial No. 09/955,644, which application claims the benefit of the earlier filing date of our provisional application No. 60/234,248, filed September 19, 2000.

That we have read, and understand, the Office actions and references applied therein, including the Tan et al. patent (U.S. Patent No. 6,077,527), and understand that the Examiner has rejected the claims in view of the Tan et al. patent disclosure.

That the attached document is a copy of an invention disclosure record, which document was prepared and executed prior to the June 20, 2000 publication date of Tan et al. and evidences that the claimed invention was made prior to the publication of the Tan et al. patent.

We further declare that all statements made herein of my own knowledge are true and that all statement made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by a fine or imprisonment or both under 1001 of Title 18 of the United States Code and such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

CONFIDENTIAL

The information contained in this Invention Disclosure is confidential and proprietary to National Starch and Chemical Company and is to be maintained and used solely for the benefit of National Starch and Chemical Company.



INVENTION DISCLOSURE

TITLE: NON-REACTIVE ACRYLIC PRESSURE SENSITIVE ADHESIVES FOR TRANSDERMAL DRUG DELIVERY APPLICATIONS

I. The Invention

A. Description of the Invention

This invention relates to pressure sensitive adhesive composition for use in transdermal drug delivery systems in which the adhesive composition is not crosslinked and is chemically inactive to the active (drug and excipient) ingredients contained in the transdermal formulation.

B. Purpose of the Invention

The purpose is to prepare a pressure sensitive adhesive that does not chemically react with the active (drug and excipient) ingredients contained in a transdermal formulation and maintains its adhesive properties without the need for crosslinking. No chemical reaction is meant to be no covalent bonds formed or broken between the active ingredients in the transdermal patch and/or the polymer (backborne or side group).

Current adhesives are copolymers that are comprised of functional monomers that are potentially reactive to the active ingredients. Functional monomers are meant to include but not limited to carboxylic acid, hydroxyl, epoxy, and acetate functionality e.g. acrylic acid, methacrylic acid, 2-hydroxyethyl acrylate, 2-hydroxyethyl methacrylate, vinyl acetate, glycidal methacrylate.

The sustained release of a pharmaceutically active drug to the skin of a human patient is of great importance. Transdermal drug delivery systems have been developed that offer this key characteristic. However, the reactivity of active ingredients within a transdermal drug delivery system with the polymer backbone or side group and with residual monomer is a threat to sustained release. Transdermal patch manufacturers are limited by this reactivity. In addition, they have excluded chemically sensitive, highly reactive drugs from their product offerings. Transdermal patch manufacturers have partially engineered around this problem by constructing the patch supersaturated with the drug. This method maintains a constant drug flux regardless of any interaction between the drug and reactive agents. This is very wasteful in that approximately only 10% of the drug in the

patch eventually enters the bloodstream. The method is economically acceptable with less expensive drugs however this method becomes cost prohibitive when used with more expensive drugs.

A second area of concern to transdermal patch formulators is the formation of new compounds within the patch as a result of a chemical reaction between the active ingredients and the adhesive. These new compounds may upset the flux of the drug. In addition, the new compound may be pharmaceutically active in the body and cause deleterious effects.

C. Attachments

- 1. Tables 1 shows the adhesive properties compared with functional acrylic and vinyl-acrylic adhesives. In addition, potential drug/excipient interactions with monomer/polymer are shown.
- 2. Laboratory notebook pages: pp. 10634-143,144; 11231-7,8,35,36,58,59; 10872-48,49.

D. Preferred Embodiment

The following adhesive (copolymer) composition gives the best performance (adhesive) and best performance (non-reactive, assumed as of this writing)

Monomer

Monomer
2-Ethylhexyl acrylate
Methyl acrylate
N-substituted acrylamide (t-Octyl acrylamide preferred)

The final adhesive is not formulated with any crosslinker. The synthesis of this material is of equal importance to the composition. The process is such to give molecular weights >600,000 Mw.

II. Literature Search Details

B. Groff conducted a literature search. The following databases were searched with the start year in (): CAPlus (1967), HCAPlus (1967), IPA (1970), IFICAT (1950), JAPIO (1976), WPIDS (1963), and Rapra (1972). Relevant literature includes:

US 4655767 USRE035474

US5186938

III. Inventorship

Eric Silverberg, Rama Chandran, Paul Foreman, Michael Philbin, Smita Shah

IV. Dates and Proof of Conception and Reduction to Practice

Project initiation worksheet written on First technical discussions occurred at a meeting on First reactions carried out on

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US Citizen

Dated:

V.	Means to Detect Infringement Nuclear Magnetic Resonance (NMR) spectroscopy and spectroscopy (FT-IR) for compositional analysis of adhesive.	Fourier-Transform	Infrared
VI.	Disclosures None		•
VII.	Marketing Manager and SBU Ellen Greenhorn, Transdermal Adhesives		
VIII.	Signatures and Comments	;	
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煮的		mul JH. Lu	De (Formy)	5) Flut 9.0	200	. 4
i <u>A)</u>	77/88.6	B) 75/42 C.	- RT 142/	15 10 10 10	p 14 C Ba	5.1
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As)	70/87.6	olite reaction	s as stated	in put pro	1	
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EVAL:			es are clear	2353	nulsed	Y.Su. 34.
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EVAL:	1. 506193 BENGED)	07A 44.4 15,180	07B 44.5 55,600	2353 40.0	10134 143.6 45.6 1.63	Y.Su. 34.
EVAL:	1.502125 BEV(42)	07A 54.4 15,180	07B 44.5	2353 40.0	10134 143 C 43.6	Y.Su. 34.
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EVAL:	1.502125 BEV(42)	07A 54.4 15,180	07B 44.5 55,600	2353 40.0	10134 143.6 45.6 1.63	Y.Su. 34.
EVAL:	Process Brulips Trul Trul Res (ppm)	07A 54.4 15,180	07B 44.5 55,600	2353 40.0	10134 143.6 45.6 1.63	Y.Su. 34.
EVAL:	Process BENCEN Total Riscippinal MA mana	- Lucys - Lucys - 27A - 44.4 - 15,180 - 1.29 - 4.4	07B 44.5 5F 600 1.55	2353 40.0	10134 143.6 45.6 1.63	1
EVAL:	Process Brulips Trul Trul Res (ppm)	2995	078 44.5 56.600 1.55 0.4	2353 40.0	10134 143.6 45.6 1.63	Y.Su. 34.
EVAL:	Process BENCED Total Rescape MA MMA ZENA	2995 32	07B 44.5 SF 600 1.55 0.4 3455 70A = 290	2353 40.0	10134 143.6 45.6 1.63	Y.Su. 34.
EVAL:	PC (MW	2995 32 4005	07B 44.5 SF 600 1.55 0.4 3455 70A = 290	2353 40.0	10134 143.6 45.6 1.63	Y.Su. 34.
EVAL:	PC (MM	2995 32 445 283,109	22+ CCUCTUS 22 ACC CLOS 07B 44.5 54.00 1.55 0.4 3455 TOA = 290 5170	2353 40.0	10134 1436 1436 15600 1.63	1.5mm; 34.
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			M	ATIO	NAL STAF	CH	Nº 11231- 35
ect No.	Ref: 11231-	78		Da	ite Started		
ect H	sh Perform	4016	Mr. E.	,,, , , , ,	r Oca J	- TOD. 9 = 52.5 / ma= 2	
EHA:	52 5/ ma: 3	I			<u>- </u>	<u> </u>	
L	21.3/ 1.14 - 3	3.3./	10A = 10		6/ 2 Em	9= 52.5 / ma= 2	7.5/ To A= 20
. ———							
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	Objective:To observe a	ın effect on	perfrumance im	provement	w/i-OA ladder: Rofer	11224 70	
		į.	Theo. Tg -42.98°C	ł I	Theo. To 35.65°C	11231-76	
j	Initial Charge;	A=EHA 57		_	.5MA 27.5/I-OA 20		Committee Enel:
	2-Ethylhexyl acrylate	42.23	wt (g) 211.15	37.23	wt (g) 186.15		1/231-36
	Methyl acryla(e	23.28	116.4	18.28	91,4		
i	t-OA	10	50	20	100		
	Ethyl scetate Acetone	64.64	323.2	64.64	323.2	- 11	
	AIBN	9.81	49.05	9.81	49.05	- 16a	
i		0.018	0.08	0.016	80.0	Media	
	initial initiator-II:	 		╟╼—┤		1 /1/1/19	
	Elhyl acetate	4.74	23.7	4.74	23,7		
	AJBN	0.019	0.095	0.019	0.095	W	
						7	t.
	Initiator SA:	1 1	·			-	
	Ethyl anetate	13.13	65.65	13.13	65.65		
	7024	0.13	0.65	0.13	0.65		
7	Monomer SA:	1				***	
	2-Ethytriexyl acrylate	15.27	76,35	1 45 00	76.75		
	Mothyl acrytale	9.22	46.1	9.22	76.35 46.1		
	Ethyl acotate	11,28	56.4	11.28	56.4		
					- 55.4		
	Solvent SA:	<u> </u>					
	Ethyl acetale Acetone	8.05	40.25	8.05	40.25		
		12.48	62.4	12.48	62.4		
i	Total weight	224.3	1121.5	├ ── ↓		····	
∤	Total solid	100.174	500.87	224.3	1121.5		
	Theoretical %solid	44.68	223.3	44.66	500.87		
· ·	5-5:	11 45)					
	Apparatus: 2L RB fla Procedure:	ask, sa ati	mer, thermom	eter, con	idenser, water ha	No CA Gammata	
l	1. Charge IC to flask				,	, or initias	
- 7	2. Start agitation, he	i. Olikka ast	g			*** **** ****	
- (3. Hold at reflux for 1	at ii to itii 10 min on	IUX. A sadal initial i	. te:			
	WICKEY . 40 HELL	, stan mo	nomer SA ove	ar i h and	-ila		The second control of
1						flux.	
	100 110	" LUIS LUIS	HILL BURRY COM	ent SA o	ver 3 h	IX.	**************************************
1	TOTAL DESCRIPTION OF D	7.3 n	Mas earl DEC		_		
i	o. Cool to room temp	 Discha 	me in an nor	priately	labeled container		••
!	9. Analysis: %Solids,	, BFV, GF	°C, Resi. mon	omers. I'	v		
· , -					·· · · · · · · · · · · · · · · · · · ·		
dysia.	2: Register	- 11	231- 35	A.	1 1 1	1. 1 1 1	
ر^. د د د	114 167	4.	Dryp.	・ヘーナ	4.0 6.4	L Several +	um 5 mins after
there	1443, NO CX	therm	Fo.	~	1,54.1	~ 7	Renter 355 has
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Nº 11231- 36

			t, in			*** * ***** * ****
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						Annual Section 1 and
C	omments				• • • • • • • • • • • • • • • • • • • •	
	AS) RT	- Start La	+ (RPm=2			and the same and t
	A) 77/	1876 3) 8	1.5/51.		· · · · · · · · · · · · · · · · · · ·	للاستناد كالمراجعة
	4) 75,	/cc.c . 80.	Slear		ulie en condiner	
	.,	·	101 4510	ברי כני	67/200	- a '\
X	A)	init II.	, , ,	- 80 th riting "		
- A			R+15	22.2)	\mathbf{u} . \mathbf{u} . \mathbf{u} . \mathbf{u} .	.
	a) 73/	2 times to	FONTON ALL	5 10 . 1	4 1 100 / 1	
	A1 73/		101. 1 1CT 7	الدمارهم حا	in Elit air must	A- 1 (00
	4) JH	71. (4) 7	16.5/42 6 187	142/46	mins - Complete	
		F1	t air	A = A	Coll Sympletic	120 L
•		6	. 40 . m.kss	. <i>#1 = 1</i>	(Rotter - 1/2 ob.	<u> </u>
		127L .	FEG 1, 70-2,	STRATE LA	a procedure	
		•	** **** * ****			
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	. h>A	3075	28/2/2800	3276	27.65 / 22	A AND INSTITUTE OF THE PERSON NAMED IN COLUMN
	. ZEHA	4475	Som I Som		3355 / 3300 4700 / 4640	
	708	470	=======================================	<u> </u>	4700 / 4640	
•		. , , , ,	880/ 885	250_	mining the space was to supplied the same and the same an	· · · · · · · · · · · · · · · · · · ·
1 ~ .	. 1	Analytical condit	tiana.			
GPC:		Column: Asahin:	ak GF-7M HQ(7909043) Ma WISP 717plus Column Tem	bile phase: DMAC	H0.03M HaNO3	
	1	Detector: (CD-6)	A Standard: PS			
		intection:100 of	15 Calibration: Linear(LI21) Flow rate: 1 ml/min.		And:	
		End of calculation	ample Cone.:~20 mg /4 ml m:491 Run time: 17 minutes		men column may used. Rometo of	
		Processing progr	am: P.E. Nelson Turbochron	SEC versio	43C - 76 Van	
		MOLECULAR Y	WEIGHT DISTRIBUTION	AVERAGES	from previous work.	2 11
		SAMPLE.	Mw Mn Mw/N		will use those new	11
		10634-143C 11231-7B	57 5307 45321 12.6 54 7305 46607 11.6		GPG results.	y
		11231-35A	48565R 45699 10.6	3	•	
		U[Z31-35B	[40 3598 47000 c ~			
	1.	111231-358	403698 47080 B57	.		

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								***				-	*
351 Th	B=2-EHA 52,5/MA No. Tg: \$58=-35,7,	27.5/ HOA 20 A=-20, B=-36, 0	C=-27. D=-29,	E 4 2									#* 1 ** ** ** ** ** ** ** ** ** ** ** **
	lal Charge;	358 ppin	pphyn	A (9)	mrtag	B	П	<u>c</u>		0_		E	
	Dyfrexyl acrytale Byl acrylate	37.23 18.25	33.68 14.96	168.4	39	wt (g) 195	99hrn 31.91	wt (g) 159.55	31.91	wt (g) 159.55	pphm 42.55	wt (g)	
Ю	A	20	30	74.8 150	13.29	66.45 125	19.94	99.7 125	23.27	116.35	13.29	212.75 68.45	
_	yl acetate Hono	9.81	9.81	323.2 49.05	(4.84	323.2	B4.64	323.2	20 64.84	100 323.2	20 64,64	323.2	
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heli	al Indiator-#:	╄	-				1,010	0.00	0.016	80.0	0.016	80.0	0-NV-
EU:	yl acetate	4.74	4.74	23.7	4.74	23.7	4.74	23.7					
		0.019	0.019	0.095	0.019	0,095	0.019	0.095	4.74 0.010	23.7 0.095	0.019	0.095	7
	otor SA:				<u> </u>	 	 -					0.053	1
AB		0,13	13.13 U.13	85.05 0.65	13.13	65.65	13.13	65.66	13.13	65.55	13.12	65.66	
140	omer SA:			5.03	0.13	0.65	0.13	0.65	0.13	0.65	0.13	0.65	
	hydroxyl acrylata	15.27	10,02	59.1	1€	110					·		
	nyi purytala i scutato	9.22	7.54	37.7	6.71	38.55	13.09	65,45 50.3	13.09	65.45	17 45	87.25	
		11.26	11.20	50.4	11.28	56.4	11.28	56,4	17.28	58.65 56.4	11.26	33.55 58.4	
	ent SA:					 	 					50.4	
Acard		12.40	8.05 12.48	40.25 G2.4	0.05	40.25	8.05	40.25	0.06	40.25	8.03	40.25	
2003	emper SA:			02.4	12.40	62.4	12.40	62.4	12.48	62.4	12.40	62,4	
	nostate	5	5	25							<u></u>		
HAP	P (75%)	Altra.7; Design	0.7	3,5	5	3.5	0.7	3.5	5	25	5	25 '	
	weight	224.3							٠,٦	3.5	υ.7	3.5	
	solid refical Yaceld	100,174 44.68					 						
Арре	rakus: 21. H/B Qual.	se siner, fixth	KATRIONSER, EXOPTOR	iliser, emier hai	n, SA firmets								
	rkes; Dyo IC to Oppic,					5.4.	.44e.1	A-==	```				
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7. Flo	man usama fox 6.5 h	POT OIL BLID	l.										
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NATIONAL STARCH

Nº 11231- 59

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<u> </u>	G / C						
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	71/87.6 -	Camplet Fo	notion (Re	m = Tun) = 61	.+		
				<u>3865</u>	al arms	2) - COOC	
							
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14. TOURS 40

SAME TANKANA - DEMENDER

Project No.	Date Started Table 1
Object No.	Reactive High Performance PCA
Coated	Camples 11231-58A,58B,58C,58D, and 58E on lines as
I dry mil	then laminated to 2 mil polyestes
Ran f	performance teetings. Result is followed:

Non Reactive High Performance PSA for TDD

	Solvent	2-EHA	MA	TOA	Th T. (0)
11231-58A	Acetone/EtOAc	47.5	22.5		Theory Tg(C)
11231-58B	Acetone/EtOAc	55	20	30	28 C
11231-58C	Acetone/EtOAc	45	30	25	36 C
11231-58D	Acetone/EtOAc	45	35 4	25	27 C
11231-58E	Acetone/EtOAc	60		20	29 C
	T FEBRUARY COPE		20	20	42 C

Performance on S.S panels

Sample ID	11231-58A	11231-58B	44224 500	44	
Solids			11231-58C	11231-58D	11231-58E
	43.8%	43.9%	43.7%	43.5%	44.0%
Viscosity	6,940cps	6,950cps	12,380cps	21,450cps	12,920cps
Coating Weight	17.1#/r	17.3#/r	17.3#/r	17#/r	
Peel,initial 20min.@RT (oz/in)	46,41,41 (zipped)	58,61,60 (af)	65,56,58 (af)		18.1#/r
Ava	43	59			58,59,59 (af)
Peel,24hrs OP@RT (oz/in)			69	57	59
	71,73,75 (af)	68,67,76 (af)	63,69,71 (af)	59,54,64 (af)	66,69,56 (af)
Avg	73	70	68	59	64
Peel, 1Wk_OP@RT (cz/in)	67,70,63 (af)	63,61,65 (af)	60,60,60 (af)		
Avg	67			58,54,54 (af)	68,67,60 (af)
Shear, 4PSI@RT(hr)		63	60	56	64
	6.0,6.2,6.3 (cf)	1.2,1.3,1.3 (cf)	5.7,5.8,6.0 (cf)	4.8,5.1,5.2 (cf)	0.4,0.4,0.5 (cf)
Avg	6_2	1.3	5.8	5	0.4

Note:	
(af) - adhesive failuse	
(all and a lade	
cf): whelive failure	
VORK OF: TILLEL LO	

WITNESS THIS DOCUMENT AND UNDERSTAND ITS CONTENTS

NATIONAL STARCH

Nº 10872- 49

11231-64B

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8

Fro	ject No.	Date Started
Obj	ect Non	peachive High Penjamance PSA
j		samples 11231-60,64A,64B on lines at 1 dry mil then
Asa	referred	to 2 mil PET.
		Josmana tertinge
		is followed:
·		

(T.Le) Non Reactive High Performance PSA for TDD

44004		2-EHA	MA	TOA
11231-60	Higher MW of 35B	52.5	27.5	20
11231-64A	Same as 58C	45	30	25
11231-64B	Higher MW of 58C	45	30	25
11231-58C	Control	45	30	25

Performance on S.S panels Sample ID 11231-58C 11231-60 11231-64A Solids 43.7% 47.6% 43.4% Viscosity 12,380cps 31,850 cps

43.7% 14,380 cps 24,250 cps Coating Weight 17.3#/r 18.5#/r 18.2#/r 18.1#/r Peel,initial 20min.@RT (oz/in) 65,56,58 (af) 53,54,53 (af) 52,38,26 (hz) 36,57,40 (hz) Avg 69 53 39 44 Peel,24hrs OP@RT (oz/in) 63,69,71 (af) 61,59,60 (af) 61,61,61 (af/lz) 53,56,61 (af/lz) Avg 68 60 61 57 Peel, 1Wk OP@RT (oz/in 60,60,60 (af) 63,62,64 (af) 69,69,65 (af) 69,69,61 (af) Avg 60 63 68 66 Shear, 4PSI@RT(hr) 5.7,5.8,6.0 (cf) 1.7,1.8,2.0 (cf) 7.7,8.6,7.6 (cf) 9.2,9.2,9.9 (cf) Avg 5.8 1.8

WORK OF